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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,983	09/10/2003	Timothy A. Hovanec	P 0284779 081289	6073

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,983	HOVANEC, TIMOTHY A.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-13,17-19,22,23,32 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-13,17-19,22,23,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group V, claims 10-13, 17-19, 22-23 and 32-33 on 3/20/06 is acknowledged. The traversal is on the ground(s) that the claims of Group V should not be examined separately from the claims of Groups VI and VII because the two groups of inventions are directed to similar bacterial strains. However, the extent of "similarity" is not discussed. Likewise, the extent of similarity between the nucleotide sequences it not indicated.

Regarding the alleged utility of the nucleotide sequences as oxidizing ammonia to nitrite, there is no indication on this record as to how this is to be achieved. It apparent that bacteria are required to perform this process.

In addition applicant argues that the groups are classified in the same class and subclass, the "elected" subject matter has not acquired a separate status in the art.

However this is not found persuasive because the composition as claimed encompass not only substantially different nucleotide sequences but also substantially different bacteria and references which would be applied to one composition would not necessarily anticipate or render obvious the other compositions. Evidence regarding the extent of similarity between the sequences and the respective strains will be considered regarding the issues of restriction as well as for issues of obviousness.

Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The examiner's search is not limited to the class/subclass to which the various groups belong. Clearly, a reference which would anticipate one of the above groups would not necessarily anticipate or even make obvious any of the others. If applicant does not agree with this statement, a statement by applicant on the record that the inventions are obvious over one another and that the applicant will accept a reference which renders one group anticipated or obvious will be accepted as rendering the other groups also anticipated or obvious might be persuasive to the rejoining of the claims.

The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exists. Clearly different searches and issues are involved with each group.

For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL.

Claims 10-13, 17-19, 22-23 and 32-33 are being considered on the merits to the extent that they pertain to SEQ ID NO 18 **ONLY**.

Claims 10-13, 17-19, 22-23 and 32-33 are withdrawn from consideration to the extent that they do not pertain to the elected invention. The claims should be amended to reflect the invention elected and being examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17, 19, 22 and 32-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17, 19, 22 and 32-33 are vague, indefinite and confusing in that the method of determination of stated identity for the SEQ ID NO: 18 is not set forth with any particularity in the claim designated invention. Thus, it cannot be determined whether applicant intends stringent or non-stringent conditions, for example. No new matter may be added.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-13, 17-19, 22-23 and 32-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a specific strain of an unidentified bacterial strain having at least 96% identity over the full length thereof to SEQ ID NO: 18 and this strain in

mixtures with other bacteria having 96% or 98% identity to SEQ ID NO: 1, 2, 3, 4, , 19, 20. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It does not appear that a deposit was made in this application as filed that meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Claims 17, 19, 22 and 32-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not contain any disclosure of the function of all nucleic acid sequences that are 96% identical to SEQ ID NO: 18. The claimed genus of nucleic acids is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated nucleic acids are encompassed within the scope of the claims, including partial nucleic acid sequences. The specification discloses only a single species of the claimed genus, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 17, 19, 22 and 32-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acid of SEQ ID NO: 18, does not reasonably provide enablement for all nucleic acids with at least 96% identity to SEQ ID NO: 18. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation

needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

Claims 17, 19, 22 and 32-33 are so broad as to encompass all nucleic acids with at least 96% identity to SEQ ID NO: 18 and all bacteria including nucleic acids with at least 96% identity to SEQ ID NO: 18. In addition claims 32 and 33 encompass at least two bacterial strains, one of which comprises not only these variants of SEQ ID NO: 18 but also one or more of various variants of SEQ ID NO: 1, 2, 3, 4, 19, 20. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acids and bacteria broadly encompassed by the claims. It is noted that SEQ ID NO: 18 encodes a 16S ribosomal subunit. It is known in the art that DNA encoding a bacterial 16S rDNA is used to identify and classify a bacteria isolate. Therefore, SEQ ID NO: 18 is useful for identification of other ammonia oxidizing bacteria (AOB) having a 16S rDNA of SEQ ID NO: 18. However, it is unclear at to whether the claimed variants of SEQ ID NO: 18 will be so useful as applicants have not provided guidance as to which of the nucleotides of the nucleic acid of SEQ ID NO: 18 are conserved among AOB. Furthermore, while recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modification, as encompassed by the instant claims, and the positions within a nucleic acid whether modifications can be made with a reasonable expectation of success of identifying other AOB using the claimed variants is limited and the result of such modifications is unpredictable. In addition, one skill in the art would expect any tolerance to modification for a given protein to diminish with each further and additional medication, e.g., multiple substitutions.

The specification does not support the broad scope of the claims with encompass all nucleic acids with at least 96% identity to SEQ ID NO: 18, bacteria having this sequence or further variants of SEQ ID NO: 1, 2, 3, 4, 19, 20 because the specification does not establish (A) regions of the nucleic acid structure of these various sequences that may be modified without affecting the ability to identify other ammonia-oxidizing bacteria based on the rDNA sequence;

(B) a rational and predictable scheme for modifying any nucleotides of the sequences with an expectation of obtaining the desired biological function, i.e., hybridizing to other AOB rDNA sequences as well as ammonia oxidation capability and
(C) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus applicants have not provided sufficient guidance to enable of the of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including all nucleic acids with at least 96% identity to SEQ ID NO: 18 and bacteria comprising this sequences as well as further bacteria comprising variants of SEQ ID NO: 1, 2, 3, 4, 19, 20. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA) 1970). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skill in the art in unnecessarily, and improperly, extensive and undue. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651

need to change this. Copy from dvid steadman

Claims 1-7, 16, 18 and 20-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a alleviating or preventing accumulation of ammonia in certain environments such as a household aquarium, does not reasonably provide enablement for the alleviation or prevention of the accumulation of ammonia in any and all environments by providing certain bacteria. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2nd 1400 (Fed. Cir. 1988) as to undue experimentation.

The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art;
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and ,
8) the relative skill of those skilled in the art.

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the art in the assessment of undue experimentation.

1) the nature of the invention; the invention is directed broadly to an anti-ammonia process but has not recited the step(s) that (a) result in preventing nor (b) have a specified end result of the treatment.

2) the breadth of the claims; the scope of the method claims includes the prevention and alleviation of ammonia in all possible environments.

3) the predictability or unpredictability of the art; the ability of preventing and alleviating the accumulation of ammonia in any and all environments appears difficult, if not impossible. It is noted that the method as claimed encompasses the administration of the bacteria to animals such as humans to prevent or alleviate the accumulation of intestinal ammonia, for example. The burden of enabling one skilled in the art to prevent accumulation of ammonia in any and all possible environments, including animals and environments toxic for the bacteria involved would be much greater than that of enabling the alleviation of accumulation in certain specific environments favorable to bacterial growth. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of preventing or alleviating ammonia accumulation in animals or environments such as paper mills, for example. Nor is there any guidance provided as to a specific protocol to be utilized in order to determine the appropriate environment.

The specification fails to enable one of ordinary skill in the art to practice the presently claimed method for preventing and for practicing same without a specific endpoint for the prevention and alleviation of the accumulation of ammonia.

4) the amount of direction or guidance presented; the specification does not provide any guidance in terms of alleviation or prevention of accumulation of ammonia as claimed.

5) the presence or absence of working examples; no working examples are provided for preventing accumulation of ammonia, for example in an animal or human, in the specification. The applicant has not provided any competent evidence or disclosed any tests that are highly predictive for the preventative effects of the instant composition. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

6) the quantity of experimentation necessary; the quantity of experimentation would be undue to one of skill in the art and amount to the trial and error type of experimentation without a priori expectation of success. Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. To support a claim to prevention or the like,

Applicant would need to provide confirmative data supporting the prevention ammonia accumulation as well as the circumstances resulting in the prevention of such accumulation.

There is no clear indication on this record that a bacterial strain having SEQ ID NO 1 is sufficient to prevent or alleviate ammonia accumulation in any environment. The bacteria are disclosed as being able to exist at concentrations no higher than 5 mg/L ammonia (Example 9) and appear to have been only cultured in a specific mixture of bacterial strains for use in reduction of ammonia concentration rather than *per se.* (Example 11). See also paragraph [0102]. In addition, it is apparent that these strains are salt-requiring, which is not addressed by the claims as written.

In view of the breadth of the claims, the chemical nature of the invention and unpredictability of preventing and alleviating accumulation of ammonia in any environment, and the lack of working examples regarding the activity as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

In consideration of each of factors 1-6, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

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Irene Marx

IRENE MARX
PRIMARY EXAMINER